Appendix A

Claim Term	BMS's Proposed Construction and Evidence in Support	Handa's Proposed Construction and Evidence in Support
characterized by an x-ray powder diffraction pattern substantially in accordance with that shown in FIG. 1 ('725 claim 1)	**PROPOSED CONSTRUCTION:** Characterized by an x-ray powder diffraction pattern that is substantially identical to those shown in FIG. 1 taking into account variations due to measurement errors and dependent upon the measurement conditions employed, but not taking into account the exact order of intensity of the peaks. **INTRINSIC EVIDENCE:** *E.g.*, '725 Patent at Abstract; *id.* at col. 4, l. 62 – col. 5, l. 19; *id.* at col. 24 l. 56 – col. 26, l. 62; *id.* at col. 41, l. 44 – col. 43, l. 30; *id.* at col. 43, l. 33 – col. 45, l. 32; *id.* at col. 48, ll. 39–44; *id.* at Figs. 1–7; *id.* at claims 1–3, 5, 9–10, 12. *E.g.*, '103 Patent at Abstract; *id.* at col. 5, ll. 15–16; *id.* at col. 24, l. 61 – col. 25, l. 67; *id.* at col. 26, ll. 4–21; *id.* at col. 42, l. 8 – col. 43, l. 67; *id.* at col. 44, l. 1 – col. 45, l. 67; *id.* at col 49, ll. 9–14; *id.* at Figs. 1–7; *id.* at claims 1–5. *E.g.*, '103 Patent Certified File History, BMS05025781–7199.	**PROPOSED CONSTRUCTION:** Plain and ordinary meaning/requires no construction. The usage of this term in the specification, claims, and prosecution history of the asserted patents indicate the term requires no special construction. **INTRINSIC EVIDENCE:** "In another embodiment, the monohydrate form of the compound of Formula (IV) is characterized by an X-ray powder diffraction pattern substantially in accordance with that shown in FIG. **1**." The '725 patent at 25:6-9.[1] *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 31.

[1] The asserted patents have a common specification. While all citations in this document are to the '725 patent, it is to be understood that the corresponding text from the '103 patent is also cited here.

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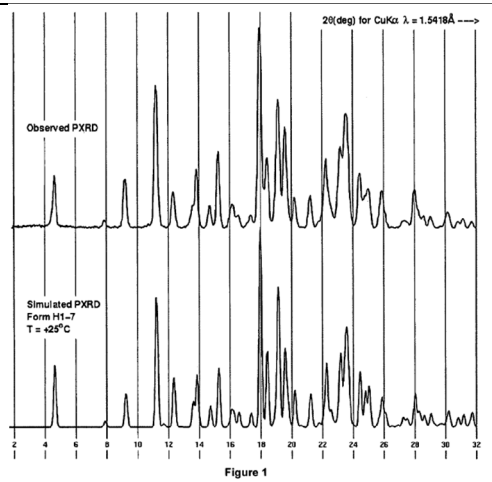
	E.g., '725 Patent Certified File History, BMS05023934–5276. **EXTRINSIC EVIDENCE:** BMS06005725–831 (*E.g.*, U.S. Patent 7,973,045 ("'045 Patent") col. 55, ll. 19 – col. 76, ll. 13; *id.* at claims 1–9). BMS06005832–884 (*E.g.*, U.S. Patent Application Publication 2022/0387431A1 ("'431 Publication")). *Bristol-Myers Squibb Co. v. Apotex, Inc., et al.*, No. 10-cv-5810 (MLC), D.I. 142 (D.N.J.). BMS06005205–207 (*The New Shorter Oxford English Dictionary on Historical Principles* (1993) entry for "characterize") BMS06005198–200 (*The New Oxford Dictionary of English* (1998) entry for "characterize") BMS06005211–213 (*Merriam-Webster's Collegiate Dictionary* (10th ed. ©2002) entry for "characterize") BMS06005201 at 203 (*The American Heritage College Dictionary* (3rd ed. 2000) entry for "accordance") BMS06005194 at 196 (*Webster's II New College Dictionary* (1995) entry for "accordance") BMS06005208–210 (*The Dictionary of Science and Technology* (2003) entry for "characterise") BMS06005201 at 204 (*The American Heritage College Dictionary* (3rd ed. 2000) entry for "substantial")	 Figure 1 The 25 Patent at Figure 1; *See also* Prosecution History of the '725 patent, 07-29-2005 Drawings at 1. "FIG. 1 shows a simulated (bottom) (calculated from atomic coordinates generated at room temperature) and experimental (top) pXRD patterns for crystalline monohydrate of the compound of formula (IV)." The '725 patent at 4:62-65. *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 6. "X-Ray Powder Diffraction One of ordinary skill in the art will appreciate that an X-ray diffraction pattern may be obtained with a measurement error that is dependent upon the measurement conditions employed. In particular, it is generally known that intensities in a X-ray diffraction pattern may fluctuate depending upon measurement conditions employed. It should be further understood that relative intensities may also vary depending upon

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	BMS06005194 at 197 (*Webster's II New College Dictionary* (1995) entry for "substantial") BMS05020189–230 (Ivanisevic) BMS01380727–780 (Brittain) BMS05020259–261 (USP 23) BMS05020262–267 (West) BMS05027245–255 (Dominguez) BMS05027279–295 (Roy) Handa's Non-Infringement Contentions, including, for example, at pp. 2–31; *id*. at Noninfringement Chart for '725 patent. Documents cited by Handa for this claim term in Handa's listing of evidence. An expert declaration in opposition to any expert declaration relied on by Handa. BMS may rely on testimony from Dr. Allan Myerson regarding the interpretation of "characterized by an x-ray powder diffraction pattern substantially in accordance with that shown in FIG. 1" to ordinarily skilled artisans at the time the patents-in-suit were filed.	experimental conditions and, accordingly, the exact order of intensity should not be taken into account. Additionally, a measurement error of diffraction angle for a conventional X-ray diffraction pattern is typically about 5% or less, and such degree of measurement error should be taken into account as pertaining to the aforementioned diffraction angles. Consequently, it is to be understood that the crystal forms of the instant invention are not limited to the crystal forms that provide X-ray diffraction patterns completely identical to the X-ray diffraction patterns depicted in the accompanying Figures disclosed herein. Any crystal forms that provide X-ray diffraction patterns substantially identical to those disclosed in the accompanying Figures fall within the scope of the present invention. The ability to ascertain substantial identities of X-ray diffraction patterns is within the purview of one of ordinary skill in the art. X-Ray powder diffraction data for the crystalline forms of Compound (IV) were obtained using a Bruker GADDS (BRUKERAXS, Inc., 5465 East Cheryl Parkway Madison, Wis. 53711 USA) (General Area Detector Diffraction System) manual chi platform goniometer. Powder samples were placed in thin walled glass capillaries of 1 mm or less in diameter; the capillary was rotated during data collection. The sample-detector distance was 17 cm. The radiation was CuKα (45 kV 111 mA, λ=1.5418 Å). Data were collected for $3<2\theta<35°$ with a sample exposure time of at least 300 seconds." The '725

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		Patent at 41:57-42-23; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 56-57. "One of ordinary skill in the art will appreciate that the monohydrate of the compound of formula (IV) may be represented by the XRPD as shown in FIG. 1 or by a representative sampling of peaks as shown in Table 1. Representative peaks taken from the XRPD of the monohydrate of the compound of formula (IV) are shown in Table 1. TABLE 1 2-Theta d(Å) Height 17.994 4.9257 915 18.440 4.8075 338 19.153 4.6301 644 19.599 4.5258 361 21.252 4.1774 148 24.462 3.6359 250 25.901 3.4371 133 28.052 3.1782 153 The XRPD is also characterized by the following list comprising 2θ values selected from the group consisting of 4.6±0.2, 11.2±0.2, 13.8±0.2, 15.2±0.2, 17.9±0.2, 19.1±0.2, 19.6±0.2, 23.2±0.2, 23.6±0.2. The XRPD is also characterized by the list of 2θ values selected from the group consisting of 18.0±0.2, 18.4±0.2, 19.2±0.2, 19.6±0.2, 21.2±0.2, 24.5±0.2, 25.9±0.2, and 28.0±0.2." The '725 Patent at 44:23-49; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 60-61. "Obviously, numerous modifications and variations of the present invention are possible in light of the above

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		teachings. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein." The '725 patent at 48-39-43; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 67. "Claims 21 and 22 were rejected under Section 112. According to MPEP 2173.05(s), claims are to be complete in themselves. However, incorporation of a specific figure is permitted "only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim." In the instant circumstances, the Figures showing the entire XRPD of the compounds provides a fingerprint of the spectra for the particular crystalline structure. Therefore, it is believed that there is no other practical way to represent the entire spectra within the claim. Additionally, it is common practice to incorporate such Figures into the claims covering crystalline forms of a compound." Prosecution History of the '725 patent, 12-18-2007 Response to Office Action at 7. **EXTRINSIC EVIDENCE:** Gilmore, C. J., *X-Ray Diffraction*, In Solid State Characterization of Pharmaceuticals, Eds. Storey, R.A. and Ymen, I., Blackwell Publishing Ltd., 2011, 35-70.

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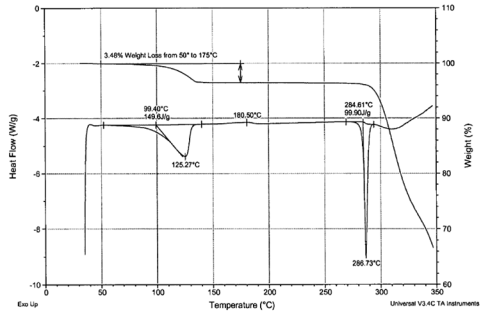
		Handa expects to rely on an expert declaration by Dr. Richard J. Matyi in opposition to BMS's proposed constructions and/or in opposition to any expert declaration relied on by BMS.
characterized by differential scanning calorimetry thermogram and a thermogravimetric analysis substantially in accordance with that shown in FIG. 2 ('725 claim 2; '103 claim 2)	**PROPOSED CONSTRUCTION:** Characterized by differential scanning calorimetry thermogram and thermogravimetric analysis patterns that are substantially identical to those shown in FIG. 2, having one peak at approximately 287° C and one broad peak between approximately 95° C and approximately 130° C. **INTRINSIC EVIDENCE:** *E.g.*, '725 Patent at Abstract; *id.* at col. 4, l. 62 – col. 5, l. 19; *id.* at col. 24 l. 56 – col. 26, l. 62; *id.* at col. 41, l. 44 – col. 43, l. 30; *id.* at col. 43, l. 33 – col. 45, l. 32; *id.* at col. 48, ll. 39–44; *id.* at Figs. 1–7; *id.* at claims 1–3, 5, 9–10, 12. *E.g.*, '103 Patent at Abstract; *id.* at col. 5, ll. 15–16; *id.* at col. 24, l. 61 – col. 25, l. 67; *id.* at col. 26, ll. 4–21; *id.* at col. 42, l. 8 – col. 43, l. 67; *id.* at col. 44, l. 1 – col. 45, l. 67; *id.* at col 49, ll. 9–14; *id.* at Figs. 1–7; *id.* at claims 1–5. *E.g.*, '103 Patent Certified File History, BMS05025781–7199.	**PROPOSED CONSTRUCTION:** Plain and ordinary meaning/requires no construction. The usage of this term in the specification, claims, and prosecution history of the asserted patents indicate the term requires no special construction. **INTRINSIC EVIDENCE:** "In another embodiment, the monohydrate form of the compound of Formula (IV) is characterized by differential scanning calorimetry thermogram and a thermogravimetric analysis[sic] substantially in accordance with that shown in FIG. **2**" The '725 patent at 25:10-13. *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 31.  Figure 2

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	E.g., '725 Patent Certified File History, BMS05023934–5276. **EXTRINSIC EVIDENCE:** *E.g.*, '045 Patent col. 55, l. 19 – col. 76, l. 13; *id.* at claims 1–9, BMS06005725–831. *E.g.*, '431 Publication, BMS06005832–884. *Bristol-Myers Squibb Co. v. Apotex, Inc., et al.*, No. 10-cv-5810 (MLC), D.I. 142 (D.N.J.). BMS06005205–207 (*The New Shorter Oxford English Dictionary on Historical Principles* (1993) entry for "characterize") BMS06005198–200 (*The New Oxford Dictionary of English* (1998) entry for "characterize") BMS06005211–213 (*Merriam-Webster's Collegiate Dictionary* (10th ed. ©2002) entry for "characterize") BMS06005201 at 203 (*The American Heritage College Dictionary* (3rd ed. 2000) entry for "accordance") BMS06005194 at 196 (*Webster's II New College Dictionary* (1995) entry for "accordance") BMS06005208–210 (*The Dictionary of Science and Technology* (2003) entry for "characterise")	The '725 Patent at Figure 2. *See also* Prosecution History of the '725 patent, 07-29-2005 Drawings at 2. "FIG. **2** shows a DSC and TGA of the of the monohydrate crystalline form of the compound of Formula (IV)." The '725 Patent at 4:66-67; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 6. "Differential Scanning Calorimetry The DSC instrument used to test the crystalline forms was a TA Instruments® model Q1000. The DSC cell/sample chamber was purged with 100 ml/min of ultra-high purity nitrogen gas. The instrument was calibrated with high purity indium. The accuracy of the measured sample temperature with this method is within about +/-1° C., and the heat of fusion can be measured within a relative error of about +/-5%. The sample was placed into an open aluminum DSC pan and measured against an empty reference pan. At least 2 mg of sample powder was placed into the bottom of the pan and lightly tapped down to ensure good contact with the pan. The weight of the sample was measured accurately and recorded to a hundredth of a milligram. The instrument was programmed to heat at 10° C. per minute in the temperature range between 25 and 350° C. The heat flow, which was normalized by a sample weight, was plotted versus the measured sample temperature. The data were reported in units of watts/gram ("W/g). The plot was made with the endothermic peaks pointing down. The endothermic

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	BMS06005201 at 204 (*The American Heritage College Dictionary* (3rd ed. 2000) entry for "substantial") BMS06005194 at 197 (*Webster's II New College Dictionary* (1995) entry for "substantial") BMS05027263–272 (Vogel's) BMS05027279–295 (Roy) BMS05027341–345 (USP 23) Handa's Noninfringement Contentions, including, for example, at pp. 2–31; *id*. at Noninfringement Chart for '725 and '103 patents. Documents cited by Handa for this claim term in Handa's listing of evidence. An expert declaration in opposition to any expert declaration relied on by Handa. BMS may rely on testimony from Dr. Allan Myerson regarding the interpretation of "characterized by differential scanning calorimetry thermogram and a thermogravimetric analysis substantially in accordance with that shown in FIG. 2" to ordinarily skilled artisans at the time the patents-in-suit were filed.	melt peak was evaluated for extrapolated onset temperature, peak temperature, and heat of fusion in this analysis. Thermogravimetric Analysis (TGA) The TGA instrument used to test the crystalline forms was a TAInstruments® model Q500. Samples of at least 10 milligrams were analyzed at a heating rate of 10° C. per minute in the temperature range between 25°C. and about 350° C." The '725 Patent at 43:1-28; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 58-59. "The monohydrate of the compound of formula (IV) is represented by the DSC as shown in FIG. **2**. The DSC is characterized by a broad peak between approximately 95°C. and 130°C. This peak is broad and variable and corresponds to the loss of one water of hydration as seen in the TGA graph. The DSC also has a characteristic peak at approximately 287 C. which corresponds to the melt of the dehydrated form of the compound of formula (IV). The TGA for the monohydrate of the compound of Formula (IV) is shown in FIG. **2** along with the DSC. The TGA shows a 3.48% weight loss from 50° C. to 175°C. The weight loss corresponds to a loss of one water of hydration from the compound of Formula (IV)." The '725 Patent at 45:15-29; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 62.

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		"Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein." The '725 patent at 48-39-43; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 67. **EXTRINSIC EVIDENCE:** Gilmore, C. J., *Thermal Analysis – Conventional Techniques*, In Solid State Characterization of Pharmaceuticals, Eds. Storey, R.A. and Ymen, I., Blackwell Publishing Ltd., 2011, 135-186. Handa expects to rely on an expert declaration by Dr. Richard J. Matyi in opposition to BMS's proposed constructions and/or in opposition to any expert declaration relied on by BMS.
crystalline monohydrate of the compound of formula (IV) ('725 claims 1, 3, 12; '103 claim 1)	**PROPOSED CONSTRUCTION:** Plain meaning as understood by a person of ordinary skill in the art, *i.e.*, the monohydrate of the compound of formula IV in a crystalline form. **INTRINSIC EVIDENCE:** *E.g.*, '725 Patent at col. 43, l. 30 – col. 45, l. 32; *id.* at Abstract; *id.* at col. 4, l. 60 –col. 5, l. 1; *id.* at col. 24, l. 53 – col. 25, l. 43; *id*. at Figs. 1–2.	**PROPOSED CONSTRUCTION:** Plain and ordinary meaning/requires no construction The usage of this term in the specification, claims, and prosecution history of the asserted patents indicate the term requires no special construction. **INTRINSIC EVIDENCE:** "FIG. 1 shows a simulated (bottom) (calculated from atomic coordinates generated at room temperature)

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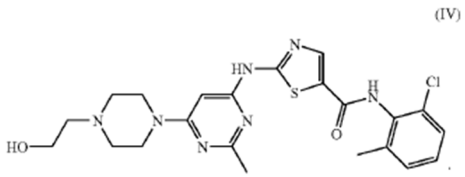
	E.g., '103 Patent at col. 44, l. 1 – col. 45, l. 67; *id*. at Abstract; *id.* at col. 5, ll. 11–36; *id.* at col. 24, l. 39 – col. 25, l. 33; *id*. at Figs. 1–2. **EXTRINSIC EVIDENCE:** *E.g.*, '933 Patent at col. 1, ll. 44–47; *id*. at col. 2, ll. 43–45; *id*. at col. 3, l. 35 – col. 4, l. 67; *id*. at col. 8, ll. 32–43. *Bristol-Myers Squibb Co. v. Apotex, Inc., et al.*, No. 10-cv-5810 (MLC), D.I. 142 (D.N.J.). *American Heritage Dictionary of the English Language* 1137 (4th ed. ©2000) (BMS01380886–888). BMS05020189–230 (Ivanisevic) BMS05020242–246 (Principles of Chemical Nomenclature) BMS05020252–258 (Remington) BMS05027237–244 (Bauer) BMS05027245–255 (Dominguez) BMS05027279–295 (Roy) BMS05027296–7302 (Sarcevica) BMS06005691–700 (S. Byrn et al., *Pharmaceutical Solids: A Strategic Approach to Regulatory*	and experimental (top) pXRD patterns for crystalline monohydrate of the compound of formula (IV). FIG. 2 shows a DSC and TGA of the of the monohydrate crystalline form of the compound of Formula (IV)." The '725 Patent at 4:62-67; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 6. "In one embodiment, the present invention provides a crystalline monohydrate of the compound of formula (IV)  The '725 Patent at 24:57-67; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 30-31. "In another embodiment, the monohydrate form of the compound of Formula (IV) is characterized by an X-ray powder diffraction pattern substantially in accordance with that shown in FIG. **1**." The '725 patent at 25:6-9.[2] *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 31.

[2] The asserted patents have a common specification. While all citations in this document are to the '725 patent, it is to be understood that the corresponding text from the '103 patent is also cited here.

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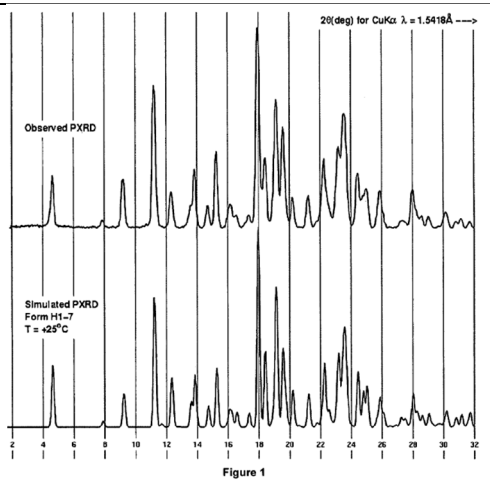
	Consideration, Pharmaceutical Research (1995) 945–54). BMS06005675–690 (L. Yu, *Amorphous Pharmaceutical Solids: Preparation, Characterization and Stabilization*, Advanced Drug Delivery Reviews 48 (2001) 27–42). BMS06005701–724 (S.R. Vippagunta, H.G. Brittain, D.J. Grant, *Crystalline Solids*, Advanced Drug Delivery Reviews 48 (2001) 3–26). Handa's Noninfringement Contentions, including, for example, at pp. 2–31; *id*. at Noninfringement Chart for '725 and '103 patents. Documents cited by Handa for this claim term in Handa's listing of evidence. An expert declaration in opposition to any expert declaration relied on by Handa. BMS may rely on testimony from Dr. Allan Myerson regarding the interpretation of "crystalline monohydrate of the compound of formula (IV)" to ordinarily skilled artisans at the time the patents-in-suit were filed.	 Figure 1 The 25 Patent at Figure 1; *See also* Prosecution History of the '725 patent, 07-29-2005 Drawings at 1. "FIG. 1 shows a simulated (bottom) (calculated from atomic coordinates generated at room temperature) and experimental (top) pXRD patterns for crystalline monohydrate of the compound of formula (IV)." The '725 patent at 4:62-65. *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 6. "In another embodiment, the monohydrate form of the compound of Formula (IV) is characterized by differential scanning calorimetry thermogram and a thermogravimetric analysis[sic] substantially in accordance with that shown in FIG. **2**" The '725 patent at 25:10-13. *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 31.

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		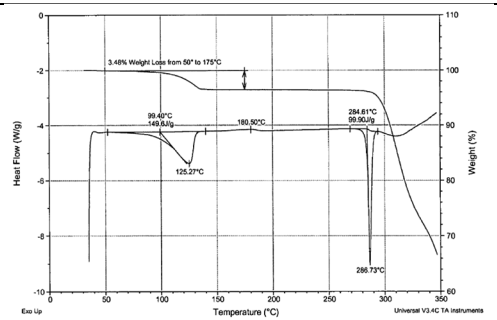 **Figure 2** The '725 Patent at Figure 2. *See also* Prosecution History of the '725 patent, 07-29-2005 Drawings at 2. "In another embodiment, the monohydrate form of the compound of Formula (IV) is characterized by an X-ray powder diffraction pattern (CuKα =1.5418 Å at a temperature of about 23° C.) comprising four or more 2θ values (alternatively, comprising five or more, six or more, or comprising 2θ values) selected from the group consisting of 18.0±0.2, 18.4±0.2, 19.2±0.2, 19.6±0.2, 21.2±0.2, 24.5±0.2, 25.9±0.2, and 28.0±0.2. In another embodiment, the monohydrate form of the compound of Formula (IV) is characterized by an X-ray powder diffraction pattern (CuKα =1.5418 Å at a temperature of about 23° C.) comprising four or more 2θ values (alternatively, comprising five or more, six or more, or comprising 2θ values) selected from the group consisting of 4.6±0.2, 11.2±0.2, 13.8±0.2, 15.2±0.2, 17.9±0.2, 19.1±0.2, 19.6±0.2, 23.2±0.2, 23.6±0.2." The '725 Patent at 25:13-28; *See also*

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		Prosecution History of the ’725 patent, 07-29-2005 Specification at 31. In another embodiment, the monohydrate form of the compound of Formula (IV) there is one water molecule per molecule of formula (IV).” The ’725 Patent at 25:41-43; *See also* Prosecution History of the ’725 patent, 07-29-2005 Specification at 32. “Preparation of: crystalline monohydrate of N-(2-chloro-6-methylphenyl)-2-(6-(4-(3-hydroxyethyl)piperazin-1-yl)-2-methylpyrimidin-4-ylamino)thiazole-5-carboxamide (IV) An example of the crystallization procedure to obtain the crystalline monohydrate form is shown here: Charge 48g of the compound of formula (IV)…” The ’725 Patent at 43:31-41; *See also* Prosecution History of the ’725 patent, 07-29-2005 Specification at 59. “Cool to 75° C., and, optionally, charge monohydrate seed crystals. Seed crystals are not essential to obtaining monohydrate, but provide better control of the crystallization.” The ’725 Patent at 43:56-58; *See also* Prosecution History of the ’725 patent, 07-29-2005 Specification at 59. “In one embodiment of the invention, for example, the compound of the formula (IV) (including, but not limited to the crystalline forms of that compound described herein, Such as the crystalline

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		monohydrate) is useful in the treatment of patients…" The '725 Patent at 28:8-12; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 36. "One of ordinary skill in the art will appreciate that the monohydrate of the compound of formula (IV) may be represented by the XRPD as shown in FIG. 1 or by a representative sampling of peaks as shown in Table 1. Representative peaks taken from the XRPD of the monohydrate of the compound of formula (IV) are shown in Table 1. TABLE 1 2-Theta d(Å) Height 17.994 4.9257 915 18.440 4.8075 338 19.153 4.6301 644 19.599 4.5258 361 21.252 4.1774 148 24.462 3.6359 250 25.901 3.4371 133 28.052 3.1782 153 The XRPD is also characterized by the following list comprising 2θ values selected from the group consisting of 4.6±0.2, 11.2±0.2, 13.8±0.2, 15.2±0.2, 17.9±0.2, 19.1±0.2, 19.6±0.2, 23.2±0.2, 23.6±0.2. The XRPD is also characterized by the list of 2θ values selected from the group consisting of 18.0±0.2, 18.4±0.2, 19.2±0.2, 19.6±0.2, 21.2±0.2, 24.5±0.2, 25.9±0.2, and 28.0±0.2." The '725 Patent at 44:23-49; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 60-61.

Appendix A (cont'd)

		"The monohydrate of the compound of formula (IV) is represented by the DSC as shown in FIG. **2**. The DSC is characterized by a broad peak between approximately 95°C. and 130°C. This peak is broad and variable and corresponds to the loss of one water of hydration as seen in the TGA graph. The DSC also has a characteristic peak at approximately 287 C. which corresponds to the melt of the dehydrated form of the compound of formula (IV). The TGA for the monohydrate of the compound of Formula (IV) is shown in FIG. **2** along with the DSC. The TGA shows a 3.48% weight loss from 50° C. to 175°C. The weight loss corresponds to a loss of one water of hydration from the compound of Formula (IV)." The '725 Patent at 45:15-29; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 62. "Claim 20 is directed to a crystalline monohydrate of the compound of formula IV. Das et al. discloses the compound of formula IV and further discloses that compounds within the reference can exist as hydrates and solvates. However, the Das et al. reference does not disclose that the compound of formula IV, as a monohydrate, would exist in a crystalline form. There is no expectation within the reference that the compound of formula IV would exist in the stoichiometry which is claimed in the instant application, that is as a one water molecule to one molecule of the compound. Furthermore, there is no expectation within the Das et al. reference that the particular monohydrate of the compound of formula

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		IV would be crystalline." Prosecution History of the '725 patent, 12-18-2007 Response to Office Action at 6. "Byrn et al. reference does not provide an expectation that any other compound not discussed therein would form a crystalline monohydrate form, nor does the reference provide any guidance as to which compounds can be provided as a crystalline hydrate. The Byrn et al. reference teaches away from the predictability of forming crystalline monohydrate forms. On page 234, the reference states that "prediction of crystal structures is not yet generally possible, we must be content with examining the crystal structures of compounds after the fact in looking for explanations of why solvates do or do not form." The Byrn et al. reference further states on page 239 that "the mere presence of water in a system is not sufficient reason to expect hydrate formation, rather, it is the activity of water that determines whether a given hydrate structure forms. We have already pointed out that some compounds do not seem to form hydrates, even though they are soluble in water." Therefore, there is no expectation, when combining the teaching of Das et al. and Byrn et al. that the compound of formula IV would form a crystalline monohydrate." Prosecution History of the '725 patent, 12-18-2007 Response to Office Action at 6. See *infra,* evidence for "compound of formula (IV)".

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		EXTRINSIC EVIDENCE: Definition of "crystalline" – "formed by crystallization: having regular arrangement of the atoms in a space lattice." Merriam-Webster's Medical Desk Dictionary, Revised Edition, 2002, 181. Definition of "monohydrate" – "a hydrate containing one molecule of water". Merriam-Webster's Medical Desk Dictionary, Revised Edition, 2002, 519. Definition of "compound" – "composed of or resulting from union of separate elements, ingredients, or parts." Merriam-Webster's Medical Desk Dictionary, Revised Edition, 2002, 160. "A pure macroscopically homogeneous substance that consists of atom or ions of different elements in definite proportions that cannot be separated by physical means, and that have properties unlike those of its constituent elements." The American Heritage Stedman's Medical Dictionary, Houghton Mifflin Company, 2002, 176. Handa expects to rely on an expert declaration by Dr. Richard J. Matyi in opposition to BMS's proposed constructions and/or in opposition to any expert declaration relied on by BMS.
compound of formula (IV) ('725 claims 1, 3, 6, 12;	**PROPOSED CONSTRUCTION:** A chemical compound made up of the atoms and structure as shown. **INTRINSIC EVIDENCE:**	**PROPOSED CONSTRUCTION:** This term recited in the previous term "crystalline monohydrate of the compound of formula (IV)," and therefore does not need to be construed separately

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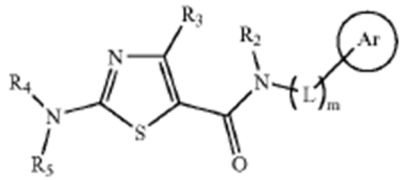
'103 claims 1–4)	This is the plain and ordinary meaning. *E.g.*, '725 Patent at col. 1, ll. 51–67; *id*. at col. 4, ll. 55–56; *id.* at col. 4, l. 60 –col. 5, l. 1; *id*. at col. 9, ll. 9–15; *id*. at col. 14, ll. 15–49; *id*. at col. 15, ll. 25–48; *id*. at col. 24, l. 53 – col. 26, l. 23; *id*. at col. 26, l. 26 – col. 27, l. 2; *id*. at col. 32, ll. 27–34; *id*. at col. 35, l. 15 – col. 39, l. 48; *id.* at col. 43, l. 30 – col. 45, l. 32; *id*. at col. 48, l. 44; *id.* at Abstract; *id*. at Figs. 1–2. *E.g.*, '103 Patent at col. 44, l. 1 – col. 45, l. 67; *id*. at Abstract; *id.* at col. 5, ll. 11–36; *id.* at col. 24, l. 39 – col. 25, l. 33; *id*. at Figs. 1–2. **EXTRINSIC EVIDENCE:** *E.g.*, '933 Patent at col. 1, ll. 44–47; *id*. at col. 2, ll. 43–45; *id*. at col. 3, l. 35 – col. 4, l. 67; *id*. at col. 8, ll. 32–43. *Bristol-Myers Squibb Co. v. Apotex, Inc., et al.*, No. 10-cv-5810 (MLC), D.I. 142 (D.N.J.). *American Heritage Dictionary of the English Language* 1137 (4th ed. ©2000) (BMS01380886–888). BMS05020189–230 (Ivanisevic) BMS05020242–246 (Principles of Chemical Nomenclature) BMS05020252–258 (Remington) BMS05027237–244 (Bauer) BMS05027245–255 (Dominguez)	therefrom. Moreover, as stated above in reference to that term, it should be accorded its plain and ordinary meaning and requires no special construction. **INTRINSIC EVIDENCE:** "Aminothiazole-aromatic amides of formula I  wherein Ar is aryl or heteroaryl, L is an optional alkylene linker, and R_2, R_3, R_4, and R_5, are as defined in the specification herein, are useful as kinase inhibitors, in particular, inhibitors of protein tyrosine kinase and p38 kinase. They are expected to be useful in the treatment of protein tyrosine kinase-associated disorders such as immunologic and oncological disorders see, U.S. Pat. No. 6,596,746 (the '746 patent), assigned to the present assignee and incorporated herein by reference, and p38 kinase-associated conditions Such as inflammatory and immune conditions, as described in U.S. patent application Ser. No. 10/773,790, filed Feb. 6, 2004, claiming priority to U.S. Provisional application Ser. No. 60/445,410, filed Feb. 6, 2003 (hereinafter the 410 application), both of which are also assigned to the present assignee and incorporated herein by reference." The '725 Patent at 1:26-50; Prosecution

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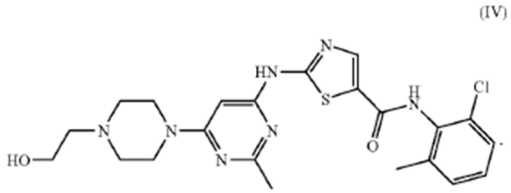
	BMS05027279–295 (Roy) BMS05027296–7302 (Sarcevica) BMS06005691–700 (S. Byrn et al., *Pharmaceutical Solids: A Strategic Approach to Regulatory Consideration*, Pharmaceutical Research (1995) 945–54). BMS06005675–690 (L. Yu, *Amorphous Pharmaceutical Solids: Preparation, Characterization and Stabilization*, Advanced Drug Delivery Reviews 48 (2001) 27–42). BMS06005701–724 (S.R. Vippagunta, H.G. Brittain, D.J. Grant, *Crystalline Solids*, Advanced Drug Delivery Reviews 48 (2001) 3–26). Handa's Noninfringement Contentions, including, for example, at pp. 2–31; *id*. at Noninfringement Chart for '725 and '103 patents. Documents cited by Handa for this claim term in Handa's listing of evidence. An expert declaration in opposition to any expert declaration relied on by Handa. BMS may rely on testimony from Dr. Allan Myerson regarding the interpretation of "compound of formula (IV)" to ordinarily skilled artisans at the time the patents-in-suit were filed.	History of the '725 patent, 07-29-2005 Specification at 1-2. "The present invention provides cyclic compounds of the following formula I and salts thereof, for use as protein tyrosine kinase inhibitors:…" US 6,596,746 ("the '746 patent") at 2:2-4. "The compound of formula (IV), N-(2-Chloro-6-methylphenyl)-2-6-4-(2-hydroxyethyl)-1-piperazinyl-2-methyl-4-pyrimidinylamino-5-thiazolecarboxamide, is an inhibitor of SRC/ABL and is useful in the treatment of oncological diseases.  (IV) The '725 Patent at 1:51-65; Prosecution History of the '725 patent, 07-29-2005 Specification at 2. "When dissolved, crystalline forms of the compound of formula (IV) loses its crystalline structure, and is therefore referred to as a solution of the compound of formula (IV)." The '725 Patent at 15:41-43; Prosecution History of the '725 patent, 07-29-2005 Specification at 20. "A therapeutically effective amount of the crystalline forms of the compound of formula (IV) is combined with a pharmaceutically acceptable carrier to produce

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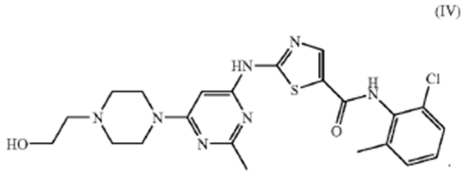
		the pharmaceutical compositions of this invention." The '725 Patent at 15:49-52; Prosecution History of the '725 patent, 07-29-2005 Specification at 20. "In one embodiment, the present invention provides a crystalline monohydrate of the compound of formula (IV)  The '725 Patent at 24:57-67; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 30-31. "Preparation of: crystalline monohydrate of N-(2-chloro-6-methylphenyl)-2-(6-(4-(3-hydroxyethyl)piperazin-1-yl)-2-methylpyrimidin-4-ylamino)thiazole-5-carboxamide (IV) An example of the crystallization procedure to obtain the crystalline monohydrate form is shown here: Charge 48g of the compound of formula (IV)…" The '725 Patent at 43:31-41; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 59. "Alternately, the monohydrate can be obtained by:

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		1) An aqueous solution of the acetate salt of compound IV was seeded with monohydrate and heated at 80° C. to give bulk monohydrate. 2) An aqueous solution of the acetate salt of compound IV was seeded with monohydrate. On standing several days at room temperature, bulk monohydrate had formed." The '725 Patent at 44:1-7; Prosecution History of the '725 patent, 07-29-2005 Specification at 60. "Claim 20 is directed to a crystalline monohydrate of the compound of formula IV. Das et al. discloses the compound of formula IV and further discloses that compounds within the reference can exist as hydrates and solvates. However, the Das et al. reference does not disclose that the compound of formula IV, as a monohydrate, would exist in a crystalline form. There is no expectation within the reference that the compound of formula IV would exist in the stoichiometry which is claimed in the instant application, that is as a one water molecule to one molecule of the compound. Furthermore, there is no expectation within the Das et al. reference that the particular monohydrate of the compound of formula IV would be crystalline." Prosecution History of the '725 patent, 12-18-2007 Response to Office Action at 6. **EXTRINSIC EVIDENCE:** Definition of "compound" – "composed of or resulting from union of separate elements, ingredients, or parts." Merriam-Webster's Medical Desk

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		Dictionary, Revised Edition, 2002, 160. "A pure macroscopically homogeneous substance that consists of atom or ions of different elements in definite proportions that cannot be separated by physical means, and that have properties unlike those of its constituent elements." The American Heritage Stedman's Medical Dictionary, Houghton Mifflin Company, 2002, 176. Handa expects to rely on an expert declaration by Dr. Richard J. Matyi in opposition to BMS's proposed constructions and/or in opposition to any expert declaration relied on by BMS.
heating and dissolving ('725 claim 6)	**PROPOSED CONSTRUCTION:** Heating the solution above room temperature so as to have some or all of the dasatinib in solution. **INTRINSIC EVIDENCE:** This is the plain and ordinary meaning. *E.g.*, '725 Patent at col. 15, ll. 41–48; col. 43, l. 30 – col. 45, l. 31. **EXTRINSIC EVIDENCE:** BMS06005666–670, *Grant & Hackh's Chemical Dictionary* (5th ed. ©1987) at 192 (entry for "dissolve"); *id*. at 275–77 (entry for "heat").	**PROPOSED CONSTRUCTION:** Plain and ordinary meaning/requires no construction The usage of this term in the specification, claims, and prosecution history of the asserted patents indicate the term requires no special construction. **INTRINSIC EVIDENCE:** "When dissolved, crystalline forms of the compound of formula (IV) loses its crystalline structure, and is therefore referred to as a solution of the compound of formula (IV)." The '725 Patent at 15:41-43; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 20. "The product (5.11 g) was dissolved in hot 80% EtOH HO (80 mL), and the solution was clarified by filtration." The '725 Patent at 39:35-37; *See also*

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	BMS06005661–665, *McGraw-Hill Dictionary of Chemistry* (1997) at 124 (entry for "dissolve"); *id*. at 179–80. BMS06005671–674, *Merriam-Webster's Collegiate Dictionary* (10th ed. ©2002) at 336 (entry for "dissolve"); *id*. at 535 (entry for "heat"). BMS05027263–272 (Vogel's) BMS05027341–345 (USP 23) Handa's Noninfringement Contentions, including, for example, at pp. 2–31; *id*. at Noninfringement Chart for '725 patent. Documents cited by Handa for this claim term in Handa's listing of evidence. An expert declaration in opposition to any expert declaration relied on by Handa. BMS may rely on testimony from Dr. Allan Myerson regarding the interpretation of "heating and dissolving" to ordinarily skilled artisans at the time the patents-in-suit were filed.	Prosecution History of the '725 patent, 07-29-2005 Specification at 53. "Dissolve the suspension by heating to approximately 75° C." The '725 Patent at 43:46; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 59. "The crystalline butanol solvate of the compound of formula (IV) is prepared by dissolving compound (IV) in 1-butanol at reflux (116-118°C.)" The '725 Patent at 45:44-46; *See also* Prosecution History of the '725 patent, 07-29-2005 Specification at 63. **EXTRINSIC EVIDENCE:** Definition of "heat" – "to become warm or hot" or "to make warm or hot". Merriam-Webster's Medical Desk Dictionary, Revised Edition, 2002, 333. Definition of "dissolve" – "to cause to pass into solution". Merriam-Webster's Medical Desk Dictionary, Revised Edition, 2002, 219. Handa expects to rely on an expert declaration by Dr. Richard J. Matyi in opposition to BMS's proposed constructions and/or in opposition to any expert declaration relied on by BMS.